

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

WYETH,

Plaintiff,

v.

LUPIN LTD. AND LUPIN
PHARMACEUTICALS, INC.,

Defendants.

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CIVIL NO.: WDQ-07-0632

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MEMORANDUM OPINION

Wyeth sued Lupin Ltd. ("Lupin") and Lupin Pharmaceuticals, Inc. ("LPI") for patent infringement and inducement of infringement. Pending are LPI's motion to dismiss and Wyeth's motion for leave to file a surreply. For the reasons discussed below, both motions will be denied.

I. Background

Wyeth owns Patents 6,274,171 B1; 6,403,120 B1; and 6,419,958 B2, all of which are entitled "Extended Release Formulation of Venlafaxine Hydrochloride." Wyeth uses the patents to manufacture and distribute EFFEXOR® XR Capsules, an extended release dosage form that contains venlafaxine hydrochloride.

Lupin is a generic drug company based in India. On September 30, 2006, Lupin filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to market and manufacture a generic

version of EFFEXOR®. Def.'s Mem. Supp. Ex. A. In its ANDA, Lupin also certified that Wyeth's patent was invalid or would not be infringed by Lupin's application ("paragraph IV certification"). See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006). LPI acted as Lupin's registered agent for the ANDA filing. LPI is the wholly owned U.S. subsidiary of Lupin that is incorporated in Virginia and has its principal place of business in Maryland.

On January 30, 2007, Wyeth received notification from Lupin that it had filed the ANDA. Wyeth filed suit against Lupin and LPI on March 12, 2007.

II. Analysis

A. Motion to Dismiss

Under Rule 12(b)(6), a party may move the court to dismiss an action if the plaintiff fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). "Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1969 (2007).

The court "should view the complaint in a light most favorable to the plaintiff," and "accept as true all well-pleaded allegations," *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993), but the court is "not bound to accept as true a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), nor "allegations that are

merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002) (citation and internal quotation marks omitted). Thus, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atlantic*, 127 S. Ct. at 1965.

Although the notice-pleading requirements of Rule 8(a)(2) are "not onerous," the plaintiff must allege facts that support each element of his claim. *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 764-65 (4th Cir. 2003).

In deciding a Rule 12(b)(6) motion, the court will consider the facts stated in the complaint and any incorporated documents. *Biospherics, Inc. v. Forbes, Inc.*, 989 F. Supp. 748, 749 (D. Md. 1997), *aff'd*, 151 F.3d 180 (4th Cir. 1998). The court may also consider documents referred to in the complaint and relied upon by the plaintiff in bringing the action. *Id.*

B. The ANDA Process

In 1984, Congress enacted the Hatch-Waxman Act (codified as amended in various sections of Titles 21 and 35 of the U.S. Code), to restore time lost to patent holders during the regulatory approval process and to create a mechanism for quickly bringing generic drugs to the market. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-74 (1990). The ANDA process allows a generic drug company to seek expedited approval of an

already-approved drug.¹ *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). When filing the ANDA, the generic drug manufacturer must certify its belief in the status of the patent. 21 U.S.C. § 355(j)(2)(A)(vii). In a paragraph IV certification, the ANDA applicant certifies that the relevant patents are either "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). After filing this certification, the generic drug manufacturer must notify the patentee, who then may decide whether to sue the applicant for infringement. *Id.* § 355(j)(5)(B)(iii).

Although a generic drug manufacturer is generally free from infringement liability during the ANDA process, see 35 U.S.C. 271(e)(1) (2006), a manufacturer that files a paragraph IV certification can be sued for patent infringement. See *id.* § 271(e)(2). Under the Hatch-Waxman Act,

[i]t shall be an act of infringement to submit . . . an [ANDA application to the FDA] . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Id. § 271(e)(2). This "somewhat artificial" ground for

¹ If the ANDA applicant resides outside the United States, "the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States." 21 C.F.R. § 314.50(a)(5) (2007).

infringement allows a court to determine whether the patents have been infringed before the specific composition has been made or distributed. *Eli Lilly*, 496 U.S. at 676; *Glaxo*, 110 F.3d at 1569.

C. Direct Infringement

LPI argues that it should be dismissed from the case because Lupin's ANDA filing was the only allegedly infringing act. LPI contends that it acted as Lupin's agent for the limited purposes of serving process and transmitting Lupin's ANDA to the FDA. This is so, LPI claims, because "only the party that *submits* the ANDA and applies for approval commits an act of infringement under § 271(e)(2)(A)." Def.'s Reply Supp. Mem. at 3.

Wyeth counters that there is no "one-defendant-per-ANDA" rule under the Hatch-Waxman Act. Pl.'s Resp. Supp. Mem. at 2. Wyeth further contends that rather than acting as a mere recipient of process, LPI acted in concert with Lupin to violate Wyeth's patents. This collaboration, Wyeth argues, means that Lupin and LPI should face liability for infringement.

In a case involving LPI and Lupin that is directly on point, a federal court denied LPI's motion to dismiss. *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 494 (E.D. Va. 2005). In *Aventis*, the Plaintiffs sued LPI and Lupin for patent infringement based on an ANDA application filed by Lupin and countersigned by LPI as Lupin's U.S. agent. *Id.* at 488. LPI

contended that it could not be liable for infringement because it did not "submit" the ANDA application. *Id.* at 492. The court rejected LPI's reasoning, relying on an agency theory of liability. *Id.* at 493. The court distinguished cases involving third-party manufacturers, as LPI's relationship with Lupin was that of "a *subsidiary* of the applicant and that subsidiary *submitted* the ANDA application to the FDA as *agent* on the foreign company's behalf." *Id.* at 492. LPI's countersignature on the ANDA application, in the court's view, provided further indication that LPI was more than a "mailbox" for Lupin's U.S. business interests. *Id.* at 493. Based on this relationship, the court denied LPI's motion to be dismissed from the case. *Id.* at 493-94.

LPI disagrees with the *Aventis* decision, arguing that other cases support a favorable outcome for LPI in this case. LPI contends that if the Court follows the *Aventis* court's agency theory, any entity that is even remotely involved with the ANDA application process would be subject to liability under the Hatch-Waxman Act.

The cases cited by LPI, *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 287 F. Supp. 2d 576 (E.D. Pa. 2002), and *SmithKline Beecham Corp. v. Pentech Pharms., Inc.*, No. 00 C 2855, 2001 WL 184804 (N.D. Ill. Feb. 20, 2001), do not support its argument for dismissal. In both cases, SmithKline sought to

amend its complaint by adding a third-party manufacturer that supplied the active ingredient for the generic drugs at issue in the ANDAs. *Geneva*, 287 F. Supp. 2d at 584-85; *Pentech*, 2001 WL 184804, at *2-3. Both courts rejected SmithKline's proposed amendment, finding that the third parties could not be held liable as direct infringers under 35 U.S.C. § 271(e)(2)(A) because they had not filed the ANDA. *Geneva*, 287 F. Supp. 2d at 584-85; *Pentech*, 2001 WL 184804, at *2-3.

Like the *Aventis* court, the Court believes that LPI's relationship with Lupin is different from the relationships at issue in the *SmithKline* cases. See *Aventis*, 403 F. Supp. 2d at 492. LPI is actively involved with filing Lupin's ANDAs with the FDA, and marketing and distributing the approved generic drugs in the United States. LPI's role in filing the ANDA is distinct from the future promises of support made by the third-party manufacturers in the *SmithKline* cases. The Court does not read § 271(e)(2) as broadly as the *Aventis* court, which placed significance on LPI's countersignature as part of its agent-principal relationship with Lupin. *Aventis*, 403 F. Supp. 2d at 493. But when a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S. and is actively involved in the ANDA process, the subsidiary also "submits" an ANDA application. See also *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 450 F. Supp. 2d 757,

760-61 (E.D. Mich. 2006) (denying a motion to dismiss an ANDA infringement case against a subsidiary and parent on a "piercing the corporate veil" agency theory).

LPI also argues that Wyeth has not alleged sufficient facts under Rule 8(a)'s liberal pleading standard. LPI's contention is premature, as Wyeth has pled sufficient facts under Rule 8(a)(2) to avoid dismissal. The first three Counts of Wyeth's Complaint adequately put LPI and Lupin on notice of Wyeth's patent infringement claims. *See Phonometrics, Inc. v. Hospitality Franchise Sys., Inc.*, 203 F.3d 790, 794 (Fed. Cir. 2000) ("[A] patentee need only plead facts sufficient to place the alleged infringer on notice.").

D. Inducement of Infringement

LPI contends that Wyeth's Fourth Count fails as a matter of law because an alleged infringer cannot be liable for inducement solely for filing or aiding and abetting the submission of an ANDA. LPI also argues that Lupin's filing of the ANDA is not an actual act of direct infringement that can actively be induced by a third party.

Wyeth counters that filing an ANDA is an act of direct infringement, and LPI's aiding and abetting of Lupin's filing is an act of induced patent infringement. Wyeth contends that the Federal Circuit has confirmed that such an action is available to patentees under the Hatch-Waxman Act, and that it has alleged

sufficient facts to bring an inducement action against LPI.

The Federal Circuit has recognized a cause of action for induced infringement under § 271(e)(2). *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003) (per curiam). But district courts, before and after *Allergan*, have disagreed about whether inducement liability exists for entities that were not the named ANDA filers.

In *AstraZeneca AB v. Mylan Laboratories, Inc.*, 265 F. Supp. 2d 213, 217 (S.D.N.Y. 2003), the court determined that Astra could not amend its complaint to include third-party manufacturers that aided a generic drug manufacturer in its ANDA filing. The *AstraZeneca* court emphasized that because the ANDA inquiry is based on whether actual infringement occurs after FDA approval, the act of aiding or abetting the filing of an ANDA cannot serve as the basis of an inducement action. *Id.* at 217-18; see also *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F. Supp. 2d 612, 616 (D. Del. 2004) (claim of inducement under § 271(e)(2) cannot be premised solely on the allegation that a defendant aided and abetted the filing of an ANDA); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 267 F. Supp. 2d 545, 549 (N.D. W. Va. 2003) (same).

In contrast, the courts in the two *SmithKline* cases allowed inducement claims to proceed. *Geneva*, 287 F. Supp. 2d at 586; *Pentech*, 2001 WL 184804, at *3. The *Pentech* court assumed that

such a claim existed, and found that SmithKline had satisfied Rule 8(a)'s liberal pleading standard. *Pentech*, 2001 WL 184804, at *3. In *Geneva*, however, the court determined that the act of filing an ANDA with a paragraph IV certification was itself an act of direct infringement. *Geneva*, 287 F. Supp. 2d at 586. Thus, inducing the filing of the ANDA was a legally cognizable claim. *Id.*

LPI argues that even if the Court found the *SmithKline* cases persuasive, their reasoning is foreclosed by the Federal Circuit's decisions in *Allergan* and *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). In *Allergan* and *Warner-Lambert*, the Federal Circuit found that allowing the inducement claims at issue would contravene the purposes of the Hatch-Waxman Act. *Allergan*, 324 F.3d at 1333; *Warner-Lambert*, 316 F.3d at 1365. In neither case did the Federal Circuit recognize or address an inducement claim for aiding and abetting the ANDA filing at issue.²

Based on its reading of *AstraZeneca*, *Pfizer*, and the Federal Circuit's ANDA cases, LPI contends that Wyeth's inducement claim fails as a matter of law. LPI's reliance on *Allergan* and *Warner-Lambert* in support of its argument is misplaced. In those cases,

² In dicta, the *Allergan* court rejected the argument that § 271(e)(2) acts as a strict liability statute. *Allergan*, 324 F.3d at 1334 n.9. Thus, the court suggested that the act of filing an ANDA is not by itself a sufficient act to produce infringement liability. *Id.*

the Federal Circuit precluded inducement claims against ANDA applicants that were not seeking FDA approval for the uses claimed in the patent and the uses were not FDA-approved. *Allergan*, 324 F.3d at 1334; *Warner-Lambert*, 316 F.3d at 1354-55. In contrast, LPI and Lupin are seeking to manufacture and distribute a generic version of Wyeth's EFFEXOR® capsules for their patented and FDA-approved use.

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To be liable for inducement, the inducing party must know or have reason to know that the activities alleged would induce infringement, and specifically intend to aid in the infringement. *Warner-Lambert*, 316 F.3d at 1363. "Inducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent." *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999). Bare allegations of activities performed in preparing the ANDA are insufficient; instead, the claim must allege aiding and abetting so that it can be determined "whether, if a particular drug were put on the market, it would infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

Wyeth has sufficiently alleged that LPI actively induced infringement under § 271(e)(2). Wyeth alleges that LPI was

actively involved in the ANDA submission process, aided and abetted the inducement of the patents-in-suit, and upon FDA approval, will infringe the patents-in-suit "by making, using, offering to sell, selling and/or importing" Lupin's proposed generic capsules. Compl. ¶¶ 35, 47, 59, 68, 69. As Wyeth's claim is not foreclosed by § 271(e)(2) and has adequately alleged an inducement claim against LPI, Wyeth has satisfied the notice pleading requirements. *See also Aventis*, 403 F. Supp. 2d at 495 (inducement of infringement claim did not fail as a matter of law); *Novo Nordisk*, 761 F. Supp. 2d at 762 (same).

E. Wyeth's Motion for Leave to File Surreply

Wyeth contends that LPI made several new points in its Reply that were not made in its original motion to dismiss. Specifically, Wyeth contends that it needs the opportunity to address LPI's new discussion of: 1) the extent of LPI's participation in the ANDA filing; 2) relevant case law; and 3) the inducement of infringement claim. As these issues were sufficiently briefed and discussed in the pleadings and accompanying briefs, a supplemental memorandum would not aid the Court. *See Khoury v. Meserve*, 268 F. Supp. 2d 600, 605-06 (D. Md. 2003). Accordingly, Wyeth's motion for leave to file a surreply will be denied.

III. Conclusion

For the reasons discussed above, LPI's motion to dismiss and Wyeth's motion for leave to file a surreply will be denied.

September 11, 2007
Date

/s/
William D. Quarles, Jr.
United States District Judge